

INJECTABLE MEDICATIONS LIST

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GENERAL INFORMATION

Reimbursement to physicians for injectable medications is made at 5% below Medicare's participating physician's allowable cost.

Office visits solely for the administration of medication are not a benefit. An injection code which covers the cost of the syringe, needle and administration of the medication may be used with the medication code when medication administration is the only reason for an office call.

When an office service is provided for other purposes, in addition to medication administration, only the office visit and a medications code may be used to bill for the service provided. Either the office visit procedure code or the injection code will be reimbursed, not both.

LIMITATIONS

1. J3490 may be used **ONLY** for new or unlisted drugs that do not have a specific code.
2. J9999 may be used **ONLY** for an unlisted anti-neoplastic drug.

Billing for J3490 or J9999:

When submitting a claim, identify the name of the drug, the strength and quantity on the claim. Claims submitted using J3490 or J9999 for any drug that has a specific billing code will be rejected.

BILLING INSTRUCTIONS

In order to comply with the provisions of the Deficit Reductions Act (DRA) of 2006, section 6002, billings for medications administered in the physician's office must include the National Drug Code (NDC) from the container from which the medication is obtained, and the number of units administered in addition to the "J" Code normally used. Billings for all drugs administered in the physician's office without the NDC information will be denied for payment beginning with the reporting deadline of January 1, 2007, specified in the DRA for single source drugs.

The following information must be provided on a CMS-1500 (08/05) Claim Form when billing for office administered drugs:

- A. NDC - Box 24D, shaded area
- B. Drug Unit Price - Box 24F, shaded area
- C. Basis of Measurement Qualifier and Units - Box 24G, shaded area. Use the following qualifiers:
 - ME - for milligrams
 - ML - for milliliters
 - GR - for grams
 - UN - for units

Outpatient hospital departments that are billing individually for drugs must also provide the NDC when billing Medicaid on the UB-04 claim form.

When billing a procedure that requires a NDC code (done under contract with a payer), enter the NDC on the line immediately below the REV Code and Procedure Code (Form locator 43), the Units preceded by

a qualifier (Form locator 46), and the Unit Price (Form locator 47).

When billing the CMS-1500 (08/05) or the UB-04 electronically, the information needs to be reported in the following X12 fields (contact your software vendor for specific information):

- 2410 LIN03= NDC number proceeded with N4 (LIN02=N4).
- 2410 CTP05-1= Units qualifier (GR, ML, ME, UN)
- 2410 CTP04= Number of units (place the number of units immediately after the units qualifier)
- 2410 CTP03= Cost or Unit Price

Medicaid currently edits if the NDC submitted is valid. The NDC must be entered with 11 digits in a 5-4-2 digit format. The first five digits of the NDC are the manufacturer's labeler code, the middle four digits are the product code, and the last two digits are the package size. If you are given an NDC that is less than 11 digits, add the missing digits as follows:

- For a 4-4-2 digit number, add a 0 to the beginning.
- For a 5-3-2 digit number, add a 0 as the sixth digit.
- For a 5-4-1 digit number, add a 0 as the tenth digit.

CODING NOTES

Please use the Coverage and Reimbursement Code Lookup tool found on the Utah Medicaid website at <http://health.utah.gov/medicaid/stplan/lookup/CoverageLookup.php>.

CRITERIA AND LIMITS FOR INJECTABLE MEDICATIONS

The pages which follow describe conditions of coverage and limits for the medications listed.

Drug	Criteria & Instructions
Avastin (J9035)	<ul style="list-style-type: none"> • Minimum age - 18 years old. • Documentation of diagnosis of metastatic carcinoma of colon or rectum OR non-squamous, non-small cell lung cancer; OR • Glioblastoma with progressive disease following prior therapy; OR • Metastatic renal cell carcinoma; OR • Macular degeneration. <p><u>Notes:</u></p> <ul style="list-style-type: none"> • Avastin is no longer FDA-approved for the treatment of breast cancer, and prior authorization requests will not be approved. <p><u>Information:</u></p> <ul style="list-style-type: none"> • To be given in clinical setting only. • Providers will bill with J code J9035, NDC number, and PA number. • Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> Initial prior is for 1 year.</p> <p><u>Re-authorization:</u> Subsequent PA is for 1 year, with an updated letter of medical necessity.</p>
Botulinum Toxins (various)	<p>Botulinum toxins are available without restriction when billing by J-code as a physician administered drug. When obtained as a pharmacy benefit, botulinum toxins require prior authorization. Those criteria can be found in the <u>Drug Criteria and Limits</u> attachment to the <u>Medicaid Pharmacy Services Manual</u>.</p>
Istodax (J9315)	<ul style="list-style-type: none"> • Minimum age 18 years • Documented diagnosis of cutaneous T-cell lymphoma • Documentation of at least one other prior system therapy <p><u>Notes:</u> To be paid through HCPCS code to an infusion center or physician's office</p> <p><u>Authorization:</u> Initial authorization will be granted for one year</p> <p><u>Re-Authorization:</u> Subsequent authorizations will be granted upon submission of an updated letter of medical necessity, showing maintenance or improvement on Istodax</p>
Krystexxa (J2507)	<ul style="list-style-type: none"> • Minimum age requirement: 18 years old. • Documented failure on or contraindication to allopurinol. • Documented failure on or contraindication to probenecid. • Documented failure on or contraindication to colchicine. • Prescribed by a rheumatologist or nephrologist informed about proper procedures. • Completion of a G6PD screen before treatment initiation (please submit results) • Dose not to exceed one 8mg infusion every 14 days. • Description of the anaphylactic measures to be taken prior to infusion. • Description of the proper resuscitative procedures in place to treat anaphylaxis. <p><u>Notes:</u></p> <ul style="list-style-type: none"> • Krystexxa is NOT indicated to treat asymptomatic gout or prophylaxis of gouty attacks. Requests for such indications will be denied. • As per indication, treatment to prevent anaphylaxis MUST be given with EACH Krystexxa infusion.

	<ul style="list-style-type: none"> This medication is only payable through j-code J2507 to a physician's office. Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> The initial prior authorization will be approved for 3 months.</p> <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> Documentation from progress notes describing positive response to treatment and lack of serious anaphylaxis or side effects. Reauthorization will not be given if a patient has more than 2 serum uric acid levels over 6mg/dl after treatment initiation. Reauthorizations will be approved for 6 months.
Orencia (J0129)	<ul style="list-style-type: none"> Diagnosis of moderate to severe rheumatoid arthritis for patient age 18 and older OR Diagnosis of Juvenile Idiopathic Arthritis for patients age 6 months and older. History of treatment failure, incomplete response or intolerance to Methotrexate or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.). The number of swollen joints, must be 6 or more (WRITE SPECIFIC NUMBER IN NOTES OR LETTER). The number of tender joints must be 9 or more (WRITE SPECIFIC NUMBER IN NOTES OR LETTER). Negative TB skin test or history of treatment for latent TB infection. Patient is absent of active bacterial or viral infection, malignancy, or immunosuppressive condition. Rheumatology consult within the last 60 days. <p><u>Notes:</u></p> <ul style="list-style-type: none"> Available as a Non-Traditional Medicaid benefit. <p><u>Information:</u></p> <ul style="list-style-type: none"> Infusion to be administered in clinic setting only. Provider will bill with J code J0129 and a PA number. Patients with ACO's will have to make arrangements with their ACO for coverage. New dispensing syringe may be obtained through pharmacy. <p><u>Authorization:</u> 1 year.</p> <p><u>Re-authorization:</u> An updated letter of medical necessity or progress notes showing improvement or maintenance.</p>
Remicade (J1745)	<p>Remicade for Crohn's Disease:</p> <ul style="list-style-type: none"> Age requirement: 6 years old and older. Diagnosis of moderate to severely active Crohn's Disease. Has failed conventional therapy (i.e. 5-aminosalicylates, antibiotic, MTX, 6-mercaptopurine, azathioprine, corticosteroids, or budesonide). Negative TB skin test or history of treatment for latent TB infection. Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition. Remicade may not be given with other biologic agents such as Interferon, experimental medications, or combinations. Remicade may not be given with Enbrel or Kineret. <p><u>Notes:</u></p> <ul style="list-style-type: none"> Available to Non-Traditional Medicaid clients. <p><u>Information:</u></p> <ul style="list-style-type: none"> To be given in clinic setting only. Provider will bill with J code J1745 and PA number. Patients with ACO's will have to make arrangements with their ACO for

	<p>coverage.</p> <p><u>Authorization:</u> 1 year.</p> <p><u>Re-authorization:</u> An updated letter of medical necessity or progress notes showing improvement or maintenance.</p>
	<p>Remicade for Plaque Psoriasis:</p> <ul style="list-style-type: none"> • Age requirement: 18 years old and older. • Diagnosis of moderate to severe plaque psoriasis. • History of incomplete response or intolerance to at least one appropriate systemic agent or photo therapy. • Negative TB skin test or history of treatment for latent TB infection. • Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition. • Dermatology consultation within the last 60 days. • Remicade may not be given with other biologic agents such as Interferon, experimental medications, or combinations. • Remicade may not be given with Enbrel or Kineret. <p><u>Information:</u></p> <ul style="list-style-type: none"> • Available to Non-Traditional Medicaid clients. • To be given in clinic setting only. • Provider will bill with J code J1745 and PA number. • Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> 1 year.</p> <p><u>Re-authorization:</u> An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.</p>
	<p>Remicade for Rheumatoid Arthritis or Psoriatic Arthritis:</p> <ul style="list-style-type: none"> • Age requirement: 18 years old and older. • Diagnosis of moderate to severe rheumatoid arthritis or psoriatic arthritis. • History of treatment, incomplete response, or intolerance to methotrexate or one other DMARD or second line drug (i.e. azathioprine, sulphadiazine, leflunomide, penicillamine, hydroxychloroquine, etc.) • The number of swollen joints must be 6 or more (WRITE SPECIFIC NUMBER IN NOTES OR LETTER). • The number of tender joints must be 9 or more (WRITE SPECIFIC NUMBER IN NOTES OR LETTER). • Negative TB skin test within the previous 12 months or history of treatment for latent TB infection. • Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition. • Rheumatology consultation within the last 60 days. • Remicade may not be given with other biologic agents such as Interferon, experimental medications, or combinations. • Remicade may not be given with Enbrel or Kineret. <p><u>Notes:</u></p> <ul style="list-style-type: none"> • Available to Non-Traditional Medicaid clients. <p><u>Information:</u></p> <ul style="list-style-type: none"> • To be given in clinic setting only. • Provider will bill with J code J1745 and PA number. • Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> 1 year.</p> <p><u>Re-authorization:</u> An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.</p>
	<p>Remicade for Ankylosing Spondylitis:</p>

	<ul style="list-style-type: none"> • Age requirement: 18 years old and older. • Documented diagnosis of ankylosing spondylitis. • Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition. • Negative TB skin test or history of treatment for latent TB infection. • Rheumatology consultation within the last 60 days. • Remicaide may not be given with other biologic agents such as Interferon, experimental medications, or combinations. <p>Notes:</p> <ul style="list-style-type: none"> • Available to Non-Traditional Medicaid clients. <p><u>Information:</u></p> <ul style="list-style-type: none"> • To be given in clinic setting only. • Provider will bill with J code J1745 and PA number. • Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> 1 year.</p> <p><u>Re-authorization:</u> An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.</p>
	<p>Remicaide for Ulcerative Colitis:</p> <ul style="list-style-type: none"> • Age requirement: 18 years old and older. • Diagnosis of moderate to severe ulcerative colitis. • Has failed conventional therapy (i.e. 5-aminosalicylates, antibiotic, MTX, 6-mercaptopurine, azathioprine, corticosteroids, or budesonide). • Negative TB skin test within the previous 12 months or history of treatment for latent TB infection. • Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition. • Remicaide may not be given with other biologic agents such as Interferon, experimental medications, or combinations. • Remicaide may not be given with Enbrel or Kineret. <p>Notes:</p> <ul style="list-style-type: none"> • Available to Non-Traditional Medicaid clients. <p><u>Information:</u></p> <ul style="list-style-type: none"> • To be given in clinic setting only. • Provider will bill with J code J1745 and PA number. • Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> 1 year.</p> <p><u>Re-authorization:</u> An updated letter of medical necessity or progress notes showing improvement or maintenance.</p>
	<p>Remicaide for Juvenile Idiopathic Arthritis:</p> <ul style="list-style-type: none"> • Age requirement: 4 years old and older. • Diagnosis of Juvenile Idiopathic Arthritis. • Documentation of failed treatment on at least one DMARD. • Negative TB skin test within the previous 12 months or history of treatment for latent TB infection. • Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition. • Rheumatology consultation within the last 60 days. • May not be given with other biologic agents such as Interferon, experimental medications, or combinations. <p>Notes:</p> <ul style="list-style-type: none"> • Available to Non-Traditional Medicaid clients. <p><u>Information:</u></p>

	<ul style="list-style-type: none"> To be given in a clinic setting only. Provider will bill with J code J1745 and PA number. Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> 1 year. <u>Re-authorization:</u> An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.</p>
Soliris (J1300)	<ul style="list-style-type: none"> Documented diagnosis of paroxysmal nocturnal hemoglobinuria. Documented failure of or intolerance to other PNH treatments, including transfusion. Review by the DUR Board. <p>Information:</p> <ul style="list-style-type: none"> To be given in a clinic setting only. Provider will bill with J code J1300, NDC number, and PA number. Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> 1 year. <u>Re-authorization:</u> 1 year with an updated letter of medical necessity and documentation of patient progress.</p>
Synagis	Effective November 1, 2012 Synagis will only be reimbursed through the pharmacy point-of-sale system. A prior authorization will still be required, criteria can be found in the <u>Drug Criteria and Limits</u> attachment to the <u>Medicaid Pharmacy Services Manual</u> .
Tysabri (J2323)	Multiple Sclerosis PA: <ul style="list-style-type: none"> Minimum age requirement: 18 years old. Documented diagnosis of Multiple Sclerosis. Documented inadequate response or intolerance to a first-line Multiple Sclerosis drug, such as Interferon or Glatiramer.
	Crohn's Disease PA: <ul style="list-style-type: none"> Minimum age requirement: 18 years old. Documented diagnosis of Crohn's disease. Documented inadequate response to conventional therapy (i.e., 5-aminosalicylates, antibiotics, MTX, 6-mercaptopurine, or azathioprine). Documented inadequate response to at least one Anti-TNF.
	<p><u>For both indications:</u></p> <p><u>Notes:</u></p> <ul style="list-style-type: none"> Available to Non-Traditional Medicaid clients. <p><u>Information:</u></p> <ul style="list-style-type: none"> To be given in a clinic setting only. Provider will bill with J code J2323 and PA number. Patients with ACO's will have to make arrangements with their ACO for coverage. <p><u>Authorization:</u> Initial authorization will be given for 1 year. <u>Re-authorization:</u> Updated letter of medical necessity indicating continued benefit from Tysabri.</p>
Vectibix (J9303)	<ul style="list-style-type: none"> Minimum age requirement: 18 years old. Diagnosis of metastatic colorectal cancer. Disease progression on or following fluoropyrimidine-, oxplatin-, and irinotecan-containing chemotherapy regimens. <p><u>Information:</u></p> <ul style="list-style-type: none"> To be given in a clinic setting only. Provider will bill with J code J9303 and PA number. Patients with ACO's will have to make arrangements with their ACO for

	<p>coverage. <u>Authorization:</u> 1 year. <u>Re-authorization:</u> Updated letter of medical necessity.</p>
Vivitrol (J2315)	<p><u>Criteria for Treatment of Alcohol Abuse OR Prevention of Relapse to Opioid Dependence :</u></p> <ul style="list-style-type: none"> • Diagnosis of alcohol abuse AND/OR diagnosis of opioid dependence. • Negative urine screen for opioids or passed naloxone challenge. • No concomitant treatment with Suboxone or Subutex. • Description of psychosocial support to be received by the patient, as indicated by chart notes or a brief letter of medical necessity. <p><u>Information:</u></p> <ul style="list-style-type: none"> • Negative urine screen for opioids is critical regardless of condition being treated – see Vivitrol’s FDA-approved prescribing information, section 5.5. • Vivitrol is to be given by substance abuse treatment providers. • Provider will bill with J code J2315, NDC 65757-0300-01 and PA number. • This drug is not available to patients with Primary Care Network coverage (PCN, yellow card). <p><u>Authorization (for both indications):</u></p> <ul style="list-style-type: none"> • Initial authorization is for 6 months. <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Updated letter of medical necessity.
Xolair (J2357)	<ul style="list-style-type: none"> • Minimum age requirement: 12 years old. • Patient must have tried all other therapies for a time period generously adequate (at least 4 months) to establish indisputable failure of each. • The request must include the following information: <ul style="list-style-type: none"> ○ Documentation of all failed therapies tried, and reason for requesting Xolair. ○ Include the desired starting dose of Xolair in the request. ○ Include the patient’s baseline IgE value and weight in the written request. <p><u>Notes:</u></p> <ul style="list-style-type: none"> • This medication is only payable through J-code J2357 to a physician’s office. • Patients with ACO’s will have to make arrangements with their ACO for coverage. • The patient must have regular appointments to receive the medication in the prescriber’s office. • The patient must remain in the office for a minimum of 90 minutes to allow for observation and treatment of anaphylaxis, if necessary. • If/when any change of dose is requested, the prescriber must indicate, in writing, the reasoning for the dose increase. <p><u>Authorization:</u> 6 months. <u>Re-authorization:</u> Updated letter of medical necessity.</p>

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